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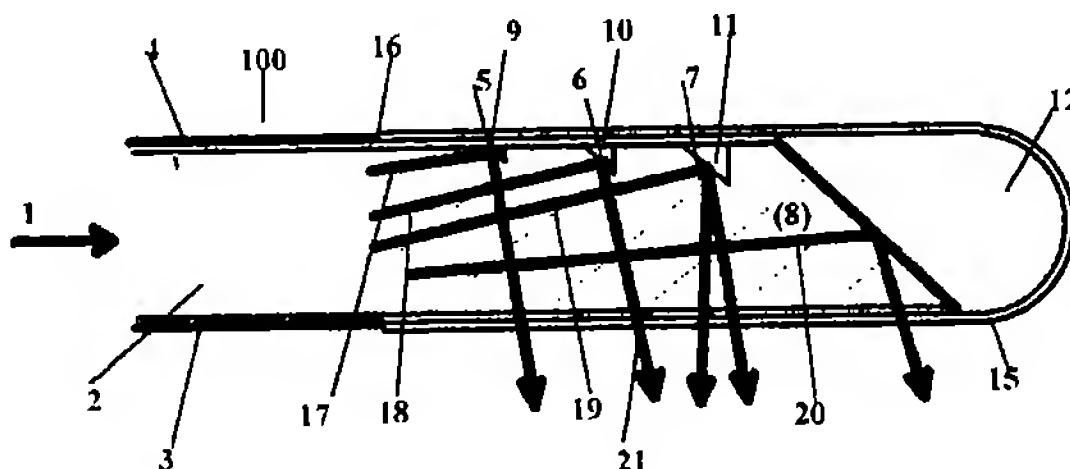
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Q Radial!medical!laser!delivery!device.

Q The present invention involves a medical delivery system capable of emitting radiation with wavelengths between 190 nm and 16 urn in one or more essentially directed, predetermined patterns. It includes at least one solid optical fiber, having a core (2) and a cladding (3) on the core. The cladding has a refractive index smaller than the core, having an input end suitably configured to connect to an appropriate radiation source and having a distal end in the proximity of which two or more grooves (5-7) are penetrating into the core. The grooves have at least partial reflector capability so as to deflect radiation thereto radially in one or more predetermined patterns. The invention also includes methods of performing medical procedures utilizing the aforesaid device.



Fig! 1

BACKGROUND!OF!THE!INVENTION

1. Field!of!the!Invention

This invention relates to a laser delivery device, and more particularly to such delivery devices that emit radiation radially from the distal end of an optical fiber.

2. Prior!Art!Statement

Technological change in laser delivery devices is rapidly taking place in the laser medical field with the onset of minimally invasive procedures such as laser laparoscopy. The laparoscopist, a physician or surgeon who performs laparoscopies, is often challenged with positioning the delivery device, i.e., the optical fiber(s), at angles radially to the laparoscope axis in order to irradiate the target perpendicularly. However, in many cases moving a laparoscope radially is very difficult or is impossible. As an alternative, the laparoscope, which is normally rigid, may have an adjustable fiber deflector called a bridge. The bridge may be adjusted at the proximal end causing radial movements to the distal end of the fibers. This adjustment is, however, limited by the bend radius of the fibers and/or the bridge device and cannot offer full capabilities. Therefore, techniques to emit radiation radially from the distal end of the fiber without bending are needed.

Reflecting tips secured on the distal fiber end, such as metal caps incorporating a mirror surface at a 45° angle relative to the fiber axis are state of the art and have been used successfully in procedures such as lithotripsy with high pulse powered (Q-switched) Yttrium Aluminium Garnet Lasers.

For many surgical procedures requiring an even illumination (such as prostate treatment or photodynamic therapy) the point source-like radiation pattern from this known device is ill suited.

The state of the art devices used in photodynamic therapy incorporate a glue, i.e. epoxy, containing cap with scattering medium dispersed in it. These caps can produce a relatively homogeneous radial pattern. However, the output is diffuse and they are somewhat limited in power handling capability due to the limitations of the glue.

In summary, the present state of the art for radial laser radiation delivery is restricted to either point sources (size of the source comparable to the fiber cross section) or to essentially diffuse radiators with limited power handling capabilities. United States Patent No. 4,740,047 describes a point source type of device using a cut fiber with a reflective surface to deflect a beam for lateral application.

While methods to control the fiber tip temperature aimed at preventing damage to the distal tip of the laser delivery device have been described in United States Patent No. 5,057,099 no control method has been described to prevent or limit damage to the tissue itself that seems applicable to treatments such as laser prostatectomy. Thus, while this recently issued patent allows for temperature control to optimize particular surgical or medical procedures, it does not address or satisfactorily resolve the need for proper lateral and radial delivery of laser beams to satisfy varied needs for varied procedures.

Thus, the prior art neither teaches nor renders obvious the present invention device set forth herein.

SUMMARY!OF!THE!INVENTION

Described is a device capable of delivering high laser power at selected angles or any angle essentially radially to the axis of an optical fiber. The fiber emits the laser radiation from a wider area at the distal end in a well directed, essentially non-diffuse pattern with a plurality of reflective surfaces, having different angles or sizes, within the fiber itself.

Surgical procedures, such as transurethral laser prostatectomy, are beneficially performed using preferred embodiments of the device. The device may comprise feedback control mechanisms from the tissue to regulate radiation delivery dosimetry with procedural requirements.

BRIEF!DESCRIPTION!OF!THE!DRAWINGS

The invention, together with further objects, advantages, aspects and features thereof, will be more clearly understood from the following description taken in connection with the accompanying drawings:

Figure 1 is a side view of a radial medical radiation delivery device using air pockets created by the core and a transparent cap for total reflection;

Figure 2 shows another radial medical radiation delivery device that can be freely positioned inside a transparent, inflatable balloon incorporating temperature sensing fibers as well, placed to irradiate the prostate;

Figure 3 is a detailed view of Figure 2 showing reflective metal coating used for deflection;

Figure 4 is a cross section of Figure 3;

Figure 5 shows a conventional state of the art Photo Dynamic Therapy Delivery device;

Figure 6 shows a delivery device with spiral grooves; and,

Figure 7! shows! a! power! control! system! operated! by! sensing! through! the! same! fiber.

DESCRIPTION! OF! THE! PREFERRED! EMBODIMENTS

It! is! an! object! of! this! invention! to! provide! a! new and! improved! radial-laser! delivery! device! to! overcome! the! disadvantages! of! prior! radial! laser! delivery! devices,! such! as! power! handling! capability, areal! coverage,! extent! of! coverage,! radially! directedness! of! radiation! from! an! extended! source,! etc. By! "radial"! and! "radially"! are! meant! extending outwardly! from! the! central! axis! of! a! fiber! and! not parallel! thereto.! In! this! application,! they! are! meant to! include! extending! outwardly! at! right! angles! as well! as! at! any! other! angles! and! to! include! full circumference! and! only! partial! circumference! radiation.

Another! object! of! this! invention! is! to! describe! a control mechanism! and! an! improved! device! method! to! carry! out! treatments! such! as! laser! prostatectomy! and! photodynamic! therapy.

Figure! 1! illustrates! a! side! view! of! present! invention! device! 100,! a! typical! preferred! embodiment of! the! invention,! at! its! distal! end.! The! optical! fiber! 1 has! a! core! 2,! a! cladding! 3! and! one! or! more protective! coating! layers! 4.! Core! 2! is! grooved! on one! side,! and! grooves! 5,! 6! and! 7! are! of! increasing size! and/or! angles,! as! shown.! Core! 2! distal! end! 8! is encapsulated! with! a! protective,! transparent! cap! 15 over! a! predetermined! length! so! as! to! cover! all! the grooves! 5,! 6! and! 7;! this! resulting! in! a! series! of! air pockets! 9,! 10,! 11! and! 12.! The! cap! can! be! affixed to! the! fiber! by! any! medically! safe! glue! 16.! If! the inclination! of! the! fronts! of! the! grooves! (facing! incoming! radiation)! measured! from! the! most! inclined ray! 17,! 18! and! 19! travelling! in! the! fiber! 1! is! chosen such! that! it! is! lower! than! the! angle! of! the! total reflection! limit! between! the! optical! fiber! core! and air, all rays! coming! through! the! fiber! from! the proximal! end! (input! end! of! the! radiation! source,! or laser)! will! be! totally! reflected! and! thus! exit! in! radial direction! as! shown! by! the! typical! arrows! such! as arrow! 21.

By! progressively! increasing! the! depth! of! each groove! towards! the! distal! end! 8! of! the! fiber! 1,! more and! more! radiation! is! diverted! from! the! axial! path into! the! radial! direction! resulting! in! the! desired extended! directed! radiation.! This! creates! a! defined, predetermined! areal! of! radiation! application! that! is much! greater! than! a! reflected! point! source.

Figure! 2! now! illustrates! how! another! such! device! 102! is! employed! to! shrink! the! prostate! gland and! thus! provide! a! free! passage! in! the! urethra.! As known,! the! prostate! gland! can! swell! and! thus! result in! an! inconvenience! for! a! high! number! of! men, particularly! at! higher! age,! in! as! much! as! the! ure-

thra! is! thus! partially! blocked! and! the! free! flow! of urine! can! be! obstructed.! It! is! known! that! by! irradiating! the! prostate,! and! thus! degenerating! and! shrinking! it! this! inconvenience! can! be! removed,! and! a free! passage! restored.! In! order! to! perform! this procedure! in! a! controlled! and! safe! manner! a present! invention! radial! medical! delivery! device 102! comprising! an! optical! fiber! 31,! a! multilumen channel! 32,! an! inflatable! balloon! 33! as! well! as temperature! sensing! fibers,! such! as! fibers! 34! and 35,! is! introduced! into! the! urether! 35.! Fiber! 31! has grooves! 41,! 42! and! 43! and! cut! end! 44, as! shown. After! inflating! the! balloon! that! is! transparent! to! the radiation! wavelength! used! in! the! procedure! (example,! 1064! nm)! radiation! is! directed! at! the! prostate 36.! The! inclinations! of! the! grooves! 41,! 42! and! 43 and! cut! tip! 44,! vary! in! this! example,! so! that! the radiation! represented! incoming! by! arrows! 45,! 46, 47! and! 48,! and! outgoing! by! arrows! 51,! 52,! 53! and 54,! converges! toward! the! prostate! 36.

The! radiation! is! thus! effectively! penetrating! the urether! wall! 38! in! a! less! concentrated! form! than! it is! hitting! the! prostate,! thus! limiting! the! damage done! to! it.

The! balloon! 33! can! be! cooled! by! gas! or! liquid to! further! protect! the! prostate! wall.! By! feeding! the temperature! reading! obtained! via! sensing! fibers! 34 and! 35! back! to! a! laser! power! control,! an! optimum radiation! level! can! be! obtained.

In! this! example! of! a! preferred! embodiment of the! radial! medical! delivery! device,! the! grooves! 41, 42,! 43 and! the! cut! tip! 44 of! the! distal! end! 50! of! the fiber,! shown! in! part! in! Figure! 3! are! at! least! partially covered! by! a! reflective! metal! 57,! 58! and! 59! (such as! gold)! to! deflect! the! radiation.! Dark! areas! 61,! 62 and! 63,! for! example,! receive! substantially! no! radiation.

Figure! 4! shows! a! cross! section! and! illustrates how,! by! flattening! the! lower! side! 60! of! the! fiber! 31 focusing! in! all! but! the! desired! dimension! and! direction! may! be! avoided.

The! superiority! over! the! present! state! of! the! art will! now! be! clear.! Compared! to! a! single! reflective (or! totally! reflective)! point! source! on! the! end! of! a fiber! the! energy! density! penetrating! through! the balloon! and! the! urether! wall! is! much! lower! and! a certain degree! of! focusing! can! be! achieved,! if desired,! towards! the! the! present! invention! for! prostate! degeneration,! a! fiber! of! synthetic! silica! could be! used! to! deliver! the! laser! power! at! 1064! nm.! The fiber! for! sensing! the! tissue! temperature! may! be! of silver! halide! semi-crystalline! material! (transmitting a! wavelength! range! between! 4! um! and! 16um).

Any! other! available! or! known! materials! may! be used! for! the! fiber! for! a! particular! application! without exceeding! the! scope! of! the! present! invention.! For example,! it! can! be! equally! possible! to! make! the radial! medical! radiation! delivery! device! employing

a silver halide fiber for the laser delivery itself.

In this case a CO₂ laser can be used as a radiation source with wavelength of around 5 μ m and typically 10.6 μ m. In this case, the same fiber through which the laser radiation passes for irradiating the tissue can also be used to measure tissue temperature as well, as illustrated in Figure 6 and Figure 7.

Figure 6 shows present invention device 106 a silver halide fiber consisting of core 91 and clad 92. In this case, circular cut angled grooves 93 and 94 and tip 96, as well as a transparent cap 95 are included. While the laser radiation 116 is targeted towards the tissue 107, the temperature radiation from tissue 108 is picked up by the fiber and transmitted via a reflector 112 formed at tip 96, in the optical path of the transmission, and fed back as shown by arrow. As shown in Figure 7, this feedback is diverted via prism 114 towards a laser control module 122 thus controlling the power output of the laser 123 in line with procedural requirements.

It is evident that in some instances it may be preferable from a manufacturing standpoint to fuse a tip of a fiber containing the grooves on to another fiber, thus effectively in the end obtaining a device similar in operative characteristics to the ones described so far, and the present invention device may include a fiber formed of such joined sections without exceeding the scope of the present invention.

Clearly, in some instances it may be advantageous to build the delivery system of more than one delivery fiber processing the characteristic as described so far in this invention, for instance in order to provide higher flexibility of the device while still maintaining a certain total cross section, a fiber bundle may be used, without exceeding the scope of the present invention. Such bundles may have fibers with identical configurations but slightly staggered to enhance transmission, or may form components of a single desired configuration, depending upon the application(s) intended.

Obviously, numerous modifications and variations of the present invention are possible in light of the above teachings. It is therefore understood that within the scope of the appended claims, the invention may be practiced otherwise than as specifically described herein.

Claims

1. A medical delivery system capable of emitting radiation with wavelengths between 190 nm and 16 urn in one or more essentially directed, predetermined patterns, which comprises:
at least one solid optical fiber, having a core and a cladding on said core and said

cladding! having! a! refractive! index! smaller! than the! core,! having! an! input! end! suitably! config- ured! to! connect! to! an! appropriate! radiation source! and! having! a! distal! end! in! the! proximity of! which! two! or! more! grooves! are! penetrating into! the! core,! said! gooves! having! at! least! par- tial! reflector! capability! so! as! to! deflect! radiation thereto! radially! in! one! or! more! predetermined patterns.

15 2. A medical delivery system as claimed in claim 1, further characterized by a cap being placed over said at least one fiber at its distal end and over said two or more grooves, and by the enclosure of gas pockets in the grooves by means of said cap.

20 3. A radial delivery system as claimed in claim 2, further characterized by filling the grooves with a material having a significantly lower reflective index than the fiber core.

25 4. A medical radiation delivery system as claimed in claim 1, wherein the grooves have a reflective coating on at least one side.

so 5. A medical radiation delivery system as claimed in claim 1, wherein said at least one fiber is a quartz glass or synthetic silica fiber and the radiation transmitted is between 180 and 3000nm.

·5 6. A medical radiation delivery system as claimed in claim 1, wherein the fiber is a silver halide fiber and the radiation transmitted is between 4 urn and 16 urn. In this case the cladding on the core may be air.

40 7. A medical radiation delivery system as claimed in claim 1, wherein the grooves are only on one side of the device.

45 8. A medical radiation delivery system as claimed in claim 1, wherein the grooves have inclinations which vary in the device so as to give a radiation pattern converging at a predetermined distance from the fiber axis.

50 9. A medical radiation delivery system as claimed in claim 1, which further includes means for collecting through the fiber, the heat radiation from the irradiated surface, thereby controlling the energy level delivered.

55 10. A medical radiation delivery device system as claimed in claim 1, which further includes one or more temperature control sensors affixed on to an inflatable balloon transparent at least

over! its! cylindrical! portion! to! the! radiation wavelength! used! and! incorporating! the! radiation! delivery! fiber! in! the! inside! of! said! inflatable! balloon.

11. A! medical! radiation! delivery! device! system! as claimed! in! claim! 10,! wherein! said! fiber! is! located! within! said! inflatable! balloon! in! a! movable! manner.

12. A! medical! radiation! delivery! system! as! claimed in claim! 1,! further! comprising! dosage! monitoring! fibers! affixed! to! an! inflatable! balloon! transparent! at! least! over! an! essential! part! of! its surface! to! the! radiation! wavelength! used.

13. A! method! of! performing! a! laser! prostatectomy procedure,! comprising:

- (a) the! inserting! of! a! cystoscope! into! the urethra
- (b) positioning! a! device! which! includes! at least! one! solid! optical! fiber,! having! a! core and! a! cladding! on! said! core! and! said! cladding! having! a! refractive! index! smaller! than the! core,! having! an! input! end! suitably! configured! to! connect! to! an! appropriate! radiation! source! and! having! a! distal! end! in! the proximity! of! which! two! or! more! grooves! are penetrating! into! the! core,! said! grooves! having! at! least! partial! reflector! capability! so! as to! deflect! radiation! thereto! radially! in! one! or more! predetermined! patterns;! and,
- (c) irradiating! the! prostate! area! to! be! degenerated.

14. The! method! of! claim! 13! wherein! said! device! is further! characterized! by! a! cap! being! placed over! said! at! least! one! fiber! at! its! distal! end! and over! said! two! or! more! grooves,! and! by! the enclosure! of! gas! pockets! in! the! grooves! by means! of! said! cap.

15. The! method! of! claim! 14! wherein! said! device! is further! characterized! by! filling! the! grooves! with a! material! having! a! significantly! lower! reflective index! than! the! fiber! core.

16. A! method! of! performing! a! prostate! degeneration! procedure! comprising:

- (a)! inserting! at! least! the! distal! end! of! a device! into! the! urether,! which! includes! at least! one! solid! optical! fiber,! having! a! core and! a! cladding! on! said! core! and! said! cladding! having! a! refractive! index! smaller! than the! core,! having! an! input! end! suitably! configured! to! connect! to! an! appropriate! radiation! source! and! having! a! distal! end! in! the proximity! of! which! two! or! more! grooves! are penetrating! into! the! core,! said! grooves! having! at! least! partial! reflector! capability! so! as to! deflect! radiation! thereto! radially! in! one! or more! predetermined! patterns;! and,

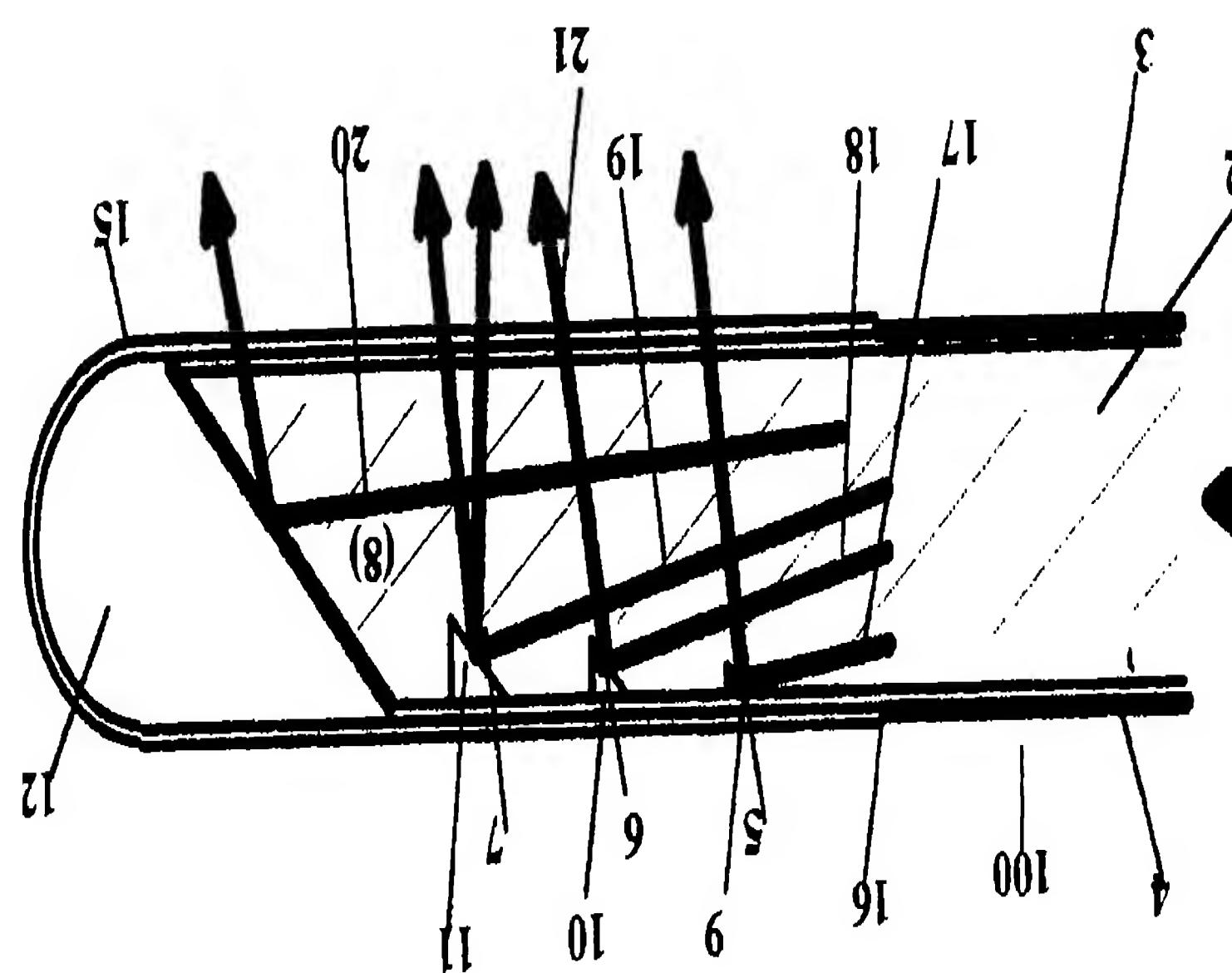
17. The! method! of! claim! 16,! wherein! said! fiber! is located! within! said! inflatable! balloon! in! a! movable! manner.

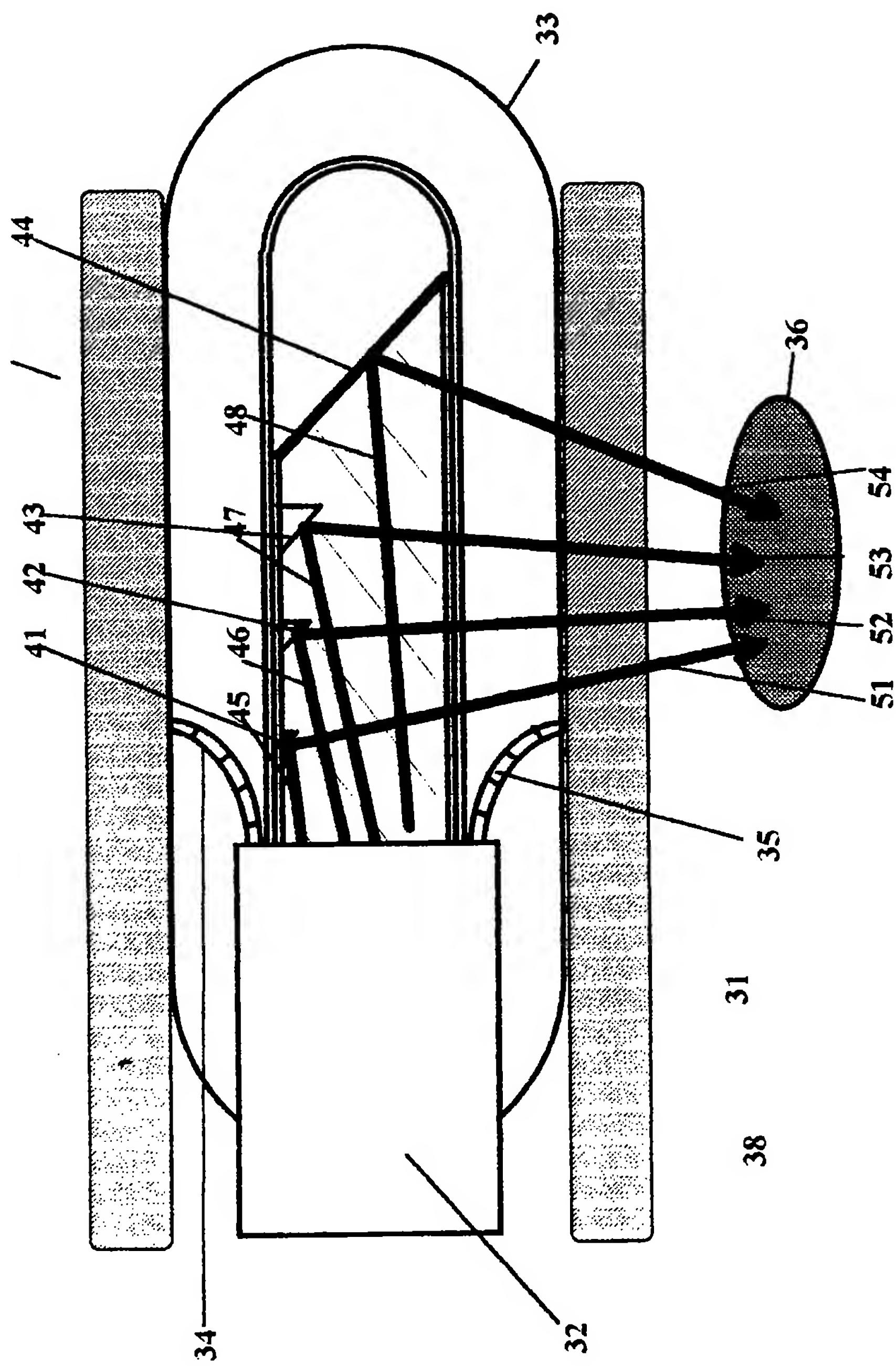
18. Method! of! performing! photodynamic! therapy, comprising:

- (a) applying! a! photosensitive! substance! to the! area! to! be! treated! or! to! the! distal! end! of the! device! set! forth! below;
- (b) inserting! a! device! which! includes! at! least one! solid! optical! fiber,! having! a! core! and! a cladding! on! said! core! and! said! cladding having! a! refractive! index! smaller! than! the core,! having! an! input! end! suitably! configured! to! connect! to! an! appropriate! radiation source! and! having! a! distal! end! in! the! proximity! of! which! two! or! more! grooves! are penetrating! into! the! core,! said! grooves! having! at! least! partial! reflector! capability! so! as to! deflect! radiation! thereto! radially! in! one! or more! predetermined! patterns;! and,
- (c) irradiating! the! tissue! to! the! intended dosage! level.

19. The! method! of! claim! 18,! further! characterized by! a! cap! being! placed! over! said! at! least! one fiber! at! its! distal! end! and! over! said! two! or more! grooves,! and! by! the! enclosure! of! gas pockets! in! the! grooves! by! means! of! said! cap.

20. The! method! of! claim! 18,! further! characterized by! filling! the! grooves! with! a! material! having! a significantly! lower! reflective! index! than! the! fiber! core.





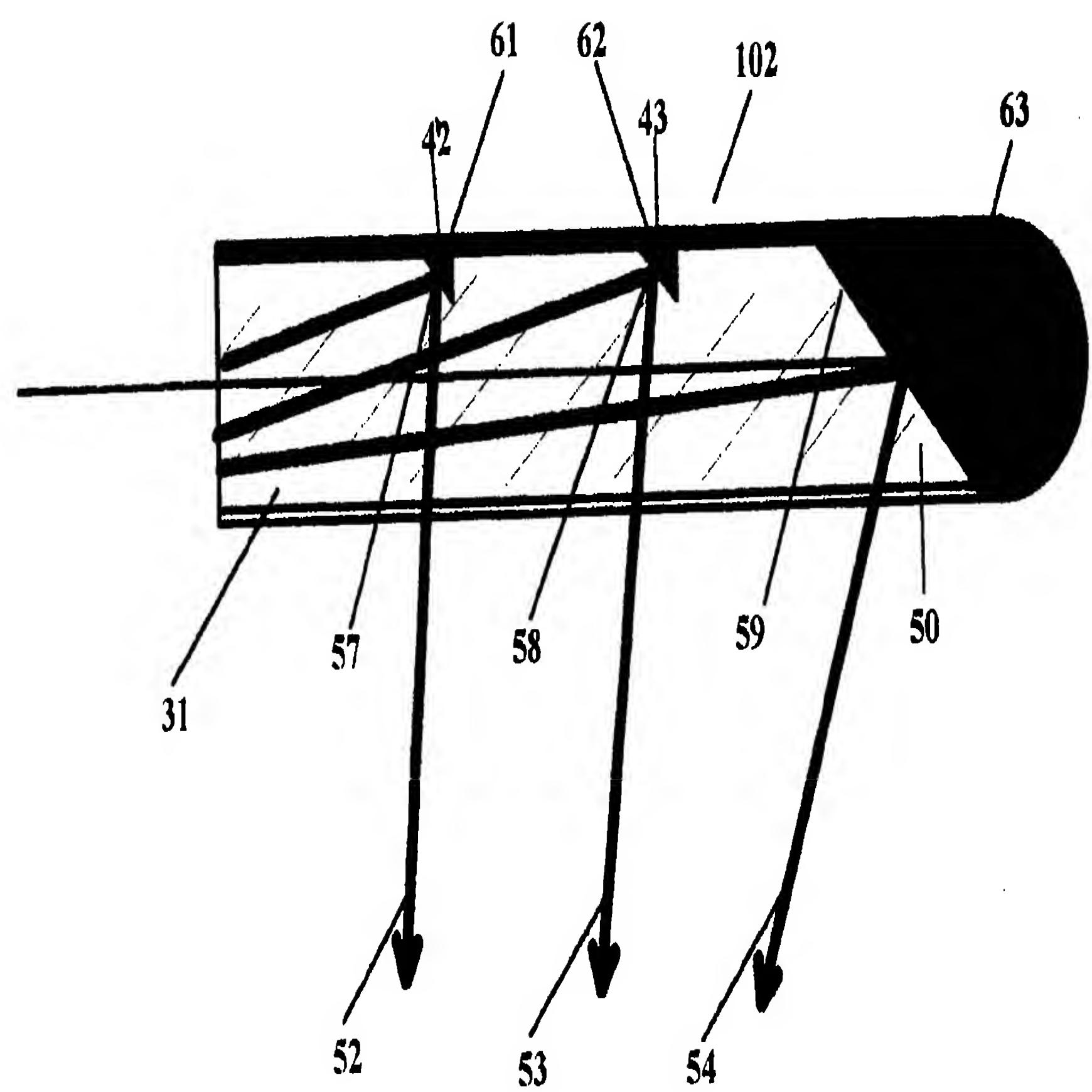


Fig 3

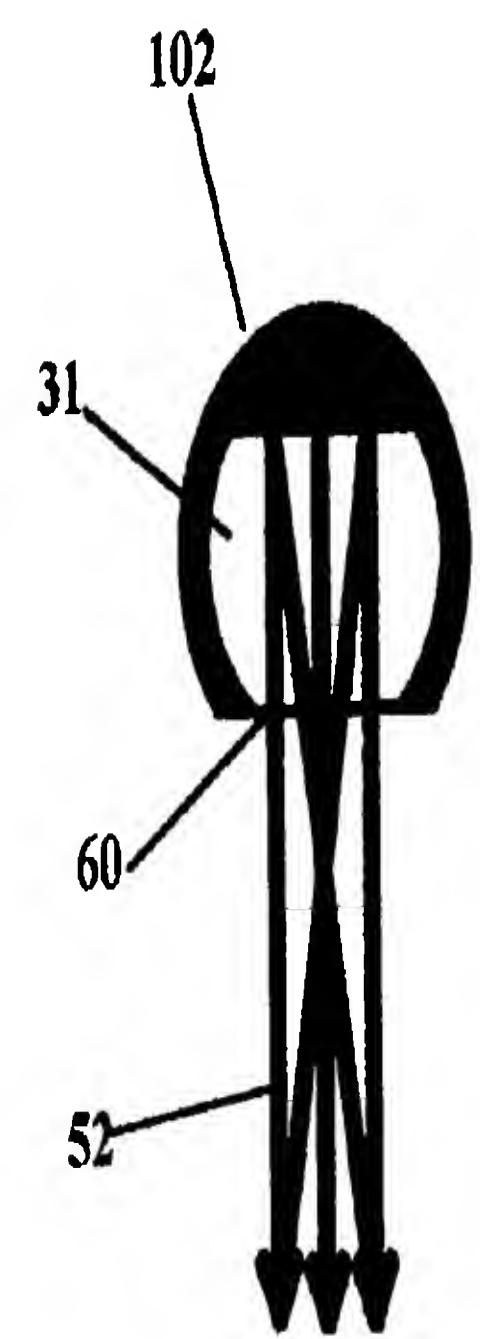


Fig 4

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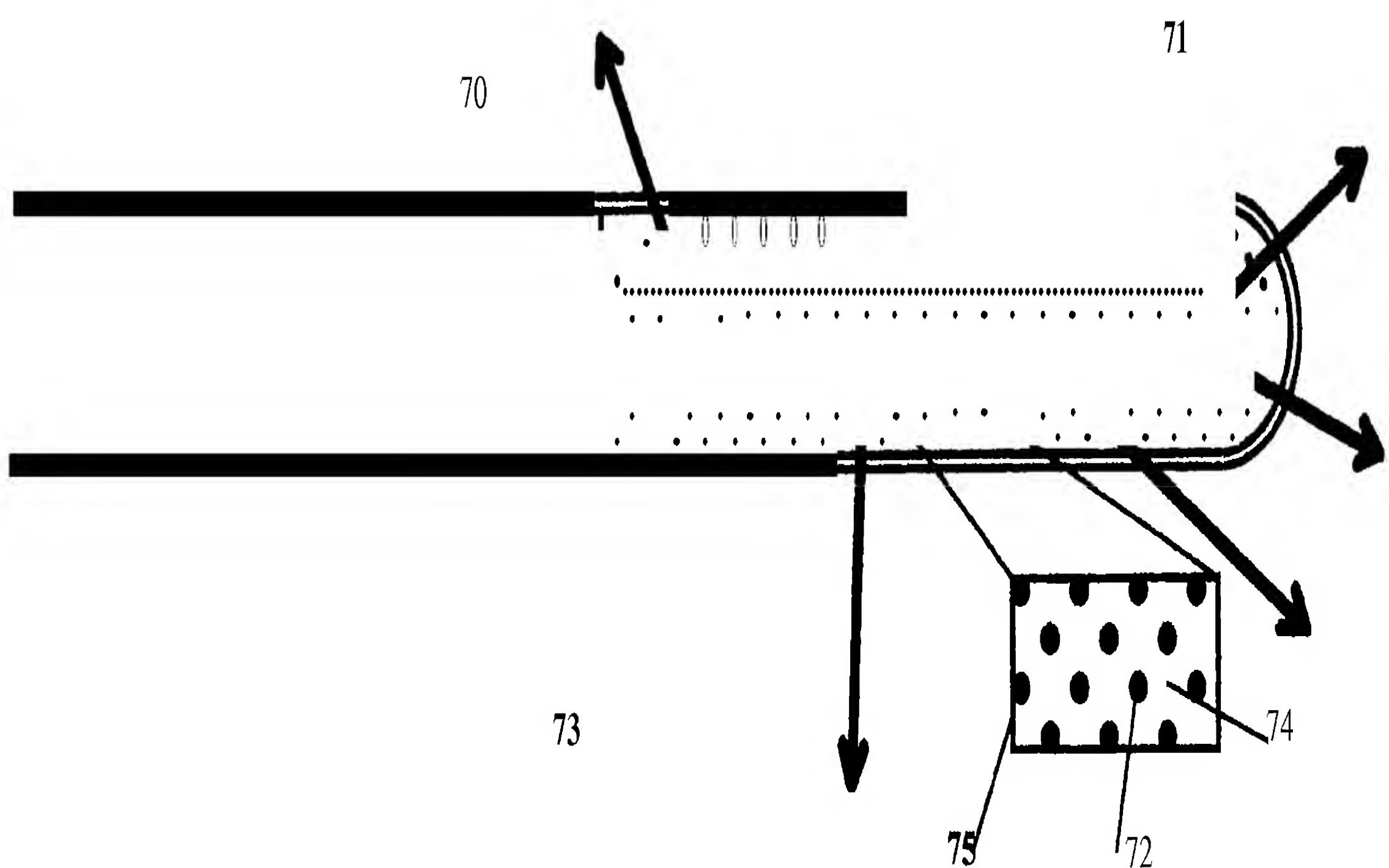
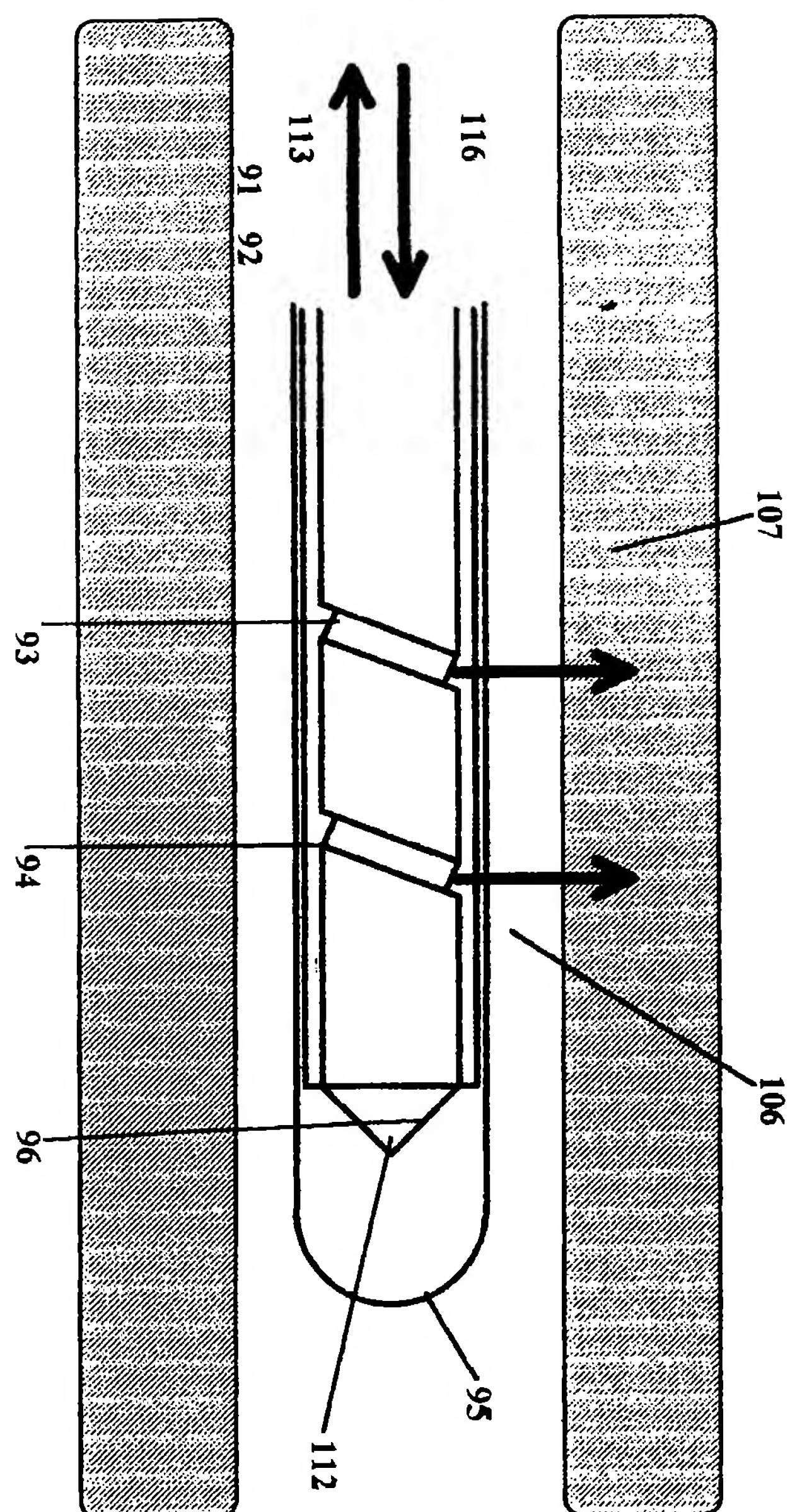
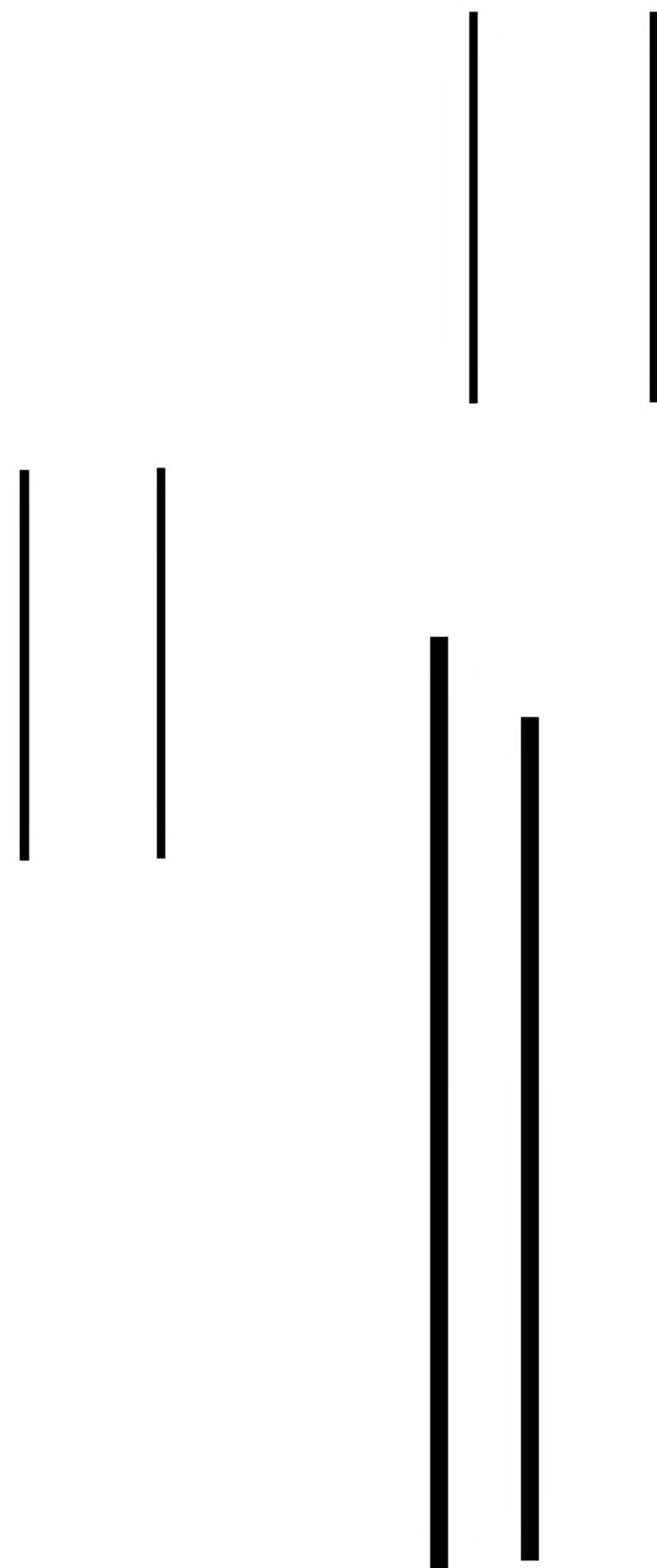


Fig 5

EP 015981984 A1



EP 0!598 984!AI





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PARTIAL EUROPEAN SEARCH REPORT

Application Number

which under Rule 45 of the European Patent Convention
shall be considered, for the purposes of subsequent
proceedings, as the European search report

DOCUMENTS CONSIDERED TO BE RELEVANT

Category	Citation of document with indication, where appropriate, of relevant passages	Relevant to claim	CLASSIFICATION OF THE APPLICATION (Int.CI5)
A	DE-A-39 26 353 (K. K. MORITA SEISAKUSHO) *! column 10, ! paragraph 3; figures 2C, 12B, 13H! *	1	A61B17/36 G02B6/28 G02B6/36
A	WO-A-90 02349 (RAYNET) *! figures! 1, 4, 5, 6! *	1	
A	WO-A-91 06251 (SURGILASE) *! page! 5, ! paragraph! 3! *	1	
A	EP-A-0 292 621 (SURGICAL LASER)		
A	US-A-4 625 724 (SUZUKI)		
A	EP-A-0 182 689 (MEDICAL LASER! R&D)		
A	EP-A-0 073 617 (PEMBERY)		

TECHNICAL FIELDS
SEARCHED (Int.CI.5)

A61B
G02B

INCOMPLETE SEARCH

The Search Division considers that the present European patent application does not comply with the provisions of the European Patent Convention to such an extent that it is not possible to carry out a meaningful search into the state of the art on the basis of some of the claims

Claims searched completely:

Claims searched incompletely:

Claims not searched:

Reason for the limitation of the search:

see sheet C

Place of search	Date of coayletloa si the rears	ExaNrr
THE HAGUE	11 February 1994	Barton, ! S
CATEGORY OF CITED DOCUMENTS		
X : particularly relevant if taken alone	T : theory or principle underlying the invention	
Y : particularly relevant if combined with another document of the same category	E : earlier patent document, but published on, or after the filing date	
A : technological background.....	D : document cited in the application	
O : non-written disclosure	L : document cited for other reasons	
P : intermediate document	& : member of the same patent family, corresponding document	



EP 93 11 0695 -C-

INCOMPLETE SEARCH

Claims searched completely : 1-12
Claims not searched : 13-20